

In re Patent Application of:

**AGRAMA**

Serial No. 10/615,963

Confirmation No. 1262

Filing Date: JULY 9, 2003

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#### REMARKS

Applicant would like to thank the Examiner for the thorough examination of the present application. The independent claims have been amended to more clearly define the present invention over the cited prior art references. The claim amendments and arguments supporting patentability of the claims are presented in detail below.

#### I. The Claimed Invention

The present invention, as recited in amended independent Claim 1, for example, is directed to a method for reducing pressure damage to skin of a person. The method comprises determining at least one location on the person susceptible to pressure damage, and adhesively securing a skin protective device to the at least one location. The skin protective device comprises a substrate having an inner surface and an outer surface opposite the inner surface, an adhesive layer substantially covering the inner surface for adhesively securing the substrate to the skin of the person, and at least one fluid-filled cell. The at least one fluid-filled cell is on the outer surface of the substrate and is positioned overlying the adhesive layer so that the substrate distributes pressure when applied to the skin of the person.

The skin protective device in accordance with the claimed invention advantageously reduces pressure damage to the skin of a person. Pressure damage occurs when the skin breaks down as a result of continuous pressure, thus forming open sores. Areas most commonly affected include the skin

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over the heel, ankle bones, tailbone, hip bones and the sacral area of the lower back.

The skin protective device distributes the pressure being applied to the skin of the person over a surface area of the substrate. Since the at least one fluid-filled cell is on the outer surface of the substrate (which is opposite the inner surface) and positioned overlying the adhesive layer, the substrate advantageously distributes pressure when applied to the skin of the person. This also increases the area over which the pressure is distributed, thereby reducing the effects of the pressure. Another benefit is that the skin protective device may be easily applied to the skin, and is held in position via the adhesive layer without causing unnecessary discomfort to the person.

Independent device Claim 14 has been amended similar to independent method Claim 1, and is directed to a skin protective device (as recited in Claim 1) for reducing pressure damage to the skin of a person. Independent device Claim 14 further recites a removable layer on the adhesive layer to protect the adhesive layer prior to application to the skin of the person.

Independent device Claim 25 is similar to independent device Claim 14, but further recites that the at least one fluid-filled cell comprises a plurality of fluid-filled cells on the outer surface of the substrate to define an exposed outermost surface for the skin protective device to cushion the skin of the person.

Independent device Claim 31 is similar to independent device Claim 14, but does not recite the substrate. Instead, an outer surface of the adhesive layer

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substantially covers the inner surface of the at least one fluid-filled cell.

## II. The Claims Are Patentable

The Examiner rejected independent Claims 1, 14, 25 and 31 as being anticipated by the Maiwald patent (U.S. Patent No. 6,096,943). Referring to FIGS. 1-7 in the Maiwald patent, the illustrated skin wound protector **14** protects a wound **12** from contact with solid objects and includes a substantially planar peripheral region **18** having top and bottom sides with adhesive **17** on the bottom for securing the protector to an area surrounding the wound.

A deformable interior region **16** rises above the peripheral region **18** top side to form a hollow cavity such that, when the adhesive **17** is secured to the area surrounding the wound, the wound resides within the cavity and is isolated from contact by solid objects. The skin wound protector **14** can be of unitary or multiple-piece construction and can be fabricated out of air-permeable, air-impermeable, clear or opaque plastic. The hollow cavity is generally dome-shaped and can further contain a medicating fluid **13** for treating the wound.

The Examiner has taken the position that the skin wound protector **14** inherently teaches a method for reducing pressure damage to the skin of a person as in the claimed invention. The Examiner characterized the substantially planar peripheral region **18** as a substrate, wherein the adhesive **17** substantially covers the inner surface thereof.

One distinction between the skin wound protector **14**

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in Maiwald and the claimed invention is with respect to the planar peripheral region **18**. In Maiwald, the planar peripheral region **18** is shaped like the brim of a hat - that is, the planar peripheral region **18** is oval shaped and open in the middle. The deformable interior region **16** is surrounded by the planar peripheral region **18**, and rises thereabove to form a hollow cavity for protecting the wound. The adhesive **17** substantially covers the inner surface of the planar peripheral region **18** and also surrounds the deformable interior region **16**.

In sharp contrast, independent Claim 1 has been amended to recite that the outer surface is opposite the inner surface. The claim already recites that the adhesive layer substantially covers the inner surface for adhesively securing the substrate to the skin of the person. Independent Claim 1 has been further amended to recite that the at least one fluid-filled cell is on the outer surface of the substrate and is positioned overlying the adhesive layer so that the substrate distributes pressure when applied to the skin of the person. In other words, the at least one fluid-filled cell is on the outer surface of the substrate, which is opposite the inner surface, and consequently, overlies the adhesive layer.

In Maiwald, the deformable interior region **16** is not positioned so that it overlies the adhesive layer **17**. Instead, the adhesive layer **17** surrounds the deformable interior region **16**. In other words, the deformable interior region **16** is laterally adjacent the adhesive layer **17** and is in direct contact with the wound to be protected.

Yet another distinction is that the skin wound

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protector 14 in the Maiwald patent serves a different purpose than the skin protective device in the claimed invention. In Maiwald, the skin wound protector 14 is for protecting a wound to the skin, after the wound has occurred. If it were not for the wound, the skin wound protector 14 would never be applied to the skin. In sharp contrast, the skin protective device in the claimed invention is for reducing pressure damage to the skin of a person. In other words, the skin protective device in the claimed invention is applied before a pressure sore develops.

Accordingly, it is submitted that amended independent Claim 1 is patentable over the Maiwald patent. Amended independent Claims 14, 25 and 31 are similar to amended independent Claim 1. Therefore, it is submitted that these claims are also patentable over the Maiwald patent. In view of the patentability of amended independent Claims 1, 14, 25 and 31, it is submitted that their dependent claims, which recite yet further distinguishing features of the invention, are also patentable. These dependent claims require no further discussion herein.

### III. CONCLUSION

In view of the amendments to the claims and the arguments provided herein, it is submitted that all the claims are patentable. Accordingly, a Notice of Allowance is requested in due course. Should any minor informalities need to be addressed, the Examiner is encouraged to contact the undersigned attorney at the telephone number listed below.

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Respectfully submitted,



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